

**Cognitive Behavioral Therapy for African Americans with Type-2  
Diabetes**

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# **Cognitive Behavioral Therapy for African Americans with Type-2 Diabetes**

## Study Protocol

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### Participating Study Sites

Emory Dunwoody Clinic  
Address: 4500 N Shallowford Rd, Atlanta, GA 30338

## Study AIMS

Aim-1: Assess and compare the feasibility, and acceptability of a Culturally-Tailored Cognitive Behavior intervention (CT-CB) for African American patients with uncontrolled diabetes (HbA1C >8%) in a 3-armed randomized controlled study (group-based CT-CB, phone-based CT-CB, and usual care).

Aim-2a: Assess the effects of the CT-CB intervention (group-based and phone-based) on secondary outcomes such as diabetes control (HbA1C), glucose self-monitoring compared with usual individual based care in clinic.

Aim-2b: Determine if the CT-CB program as tested in the two formats (group-based and phone-based) can improve diabetes outcomes and self-management among particular subsets of African American patients (with poorly controlled vs. mild uncontrolled diabetes; < 65 years vs. > 65 years; men vs women) compared with usual individual based care in clinic

## Abstract

### Study Title

#### **Cognitive Behavioral Therapy for African Americans with Type-2 Diabetes**

**Background:** African Americans are approximately twice as likely to be diagnosed with diabetes and to experience gaps in diabetes care compared to Whites. Lower health literacy and socio-economic, language, and communication barriers are all associated with disparities in diabetes care. There is evidence that behavioral interventions can help address some of these barriers. However, there is scarce data regarding the effectiveness of adapted and tailored cognitive-behavior change interventions and delivery in innovative low-cost formats for vulnerable population subgroups.

**Aim:** The aim of our study is to test the feasibility and acceptability of a Culturally-Tailored, Cognitive Behavioral intervention (CT-CB) program (in group-based and phone-based formats), compared with usual care, and to determine if the intervention can improve diabetes self-management among African American patients. We also seek to determine whether a particular subset of patients is more likely to experience improvements.

**Methods:** A randomized, parallel design trial will be initiated, with the participant as the unit of randomization, at Emory's Dunwoody Family Medicine Clinic. Forty-five African American patients with uncontrolled type 2 diabetes (HbA1C > 8 %), aged > 18 years, will be randomly assigned to undergo a six session group-based or web-based behavioral intervention (CT-CB) program or to general education (usual care). Patients with severe mental health conditions, major physical disability, or current pregnancy will be excluded. After 12 weeks, patients will be followed for an additional three months to evaluate for diminution of treatment effects. The primary outcome of our pilot is feasibility and acceptability. Feasibility is operationalized as patients enrolled as per target with a loss to follow up of no more than 20%. Acceptability is measured as attendance (>70%) of the sessions that are attended and qualitative feedback from participants. General linear mixed methods will be used to evaluate intervention effects on secondary outcomes such as HbA1C and self-management metrics. Questionnaires assessing perceived stress, anxiety, and depression will also be administered at baseline, 3, and 6 months to evaluate treatment effects. Intent-to-treat analyses will be conducted.

**Impact:** Our pilot study will determine if a socio-culturally adapted behavioral intervention for African American patients is feasible and acceptable in a primary care setting. A tailored CT-CB intervention has the potential to promote cognitive-behavior changes that can lead to improvements in clinical outcomes and may help reduce disparities in diabetes if scaled up. Findings from this project will allow us to propose a larger effectiveness study and eventually disseminate an implementation model of diabetes care for African Americans that is culturally appropriate, population-based, and patient-centered.

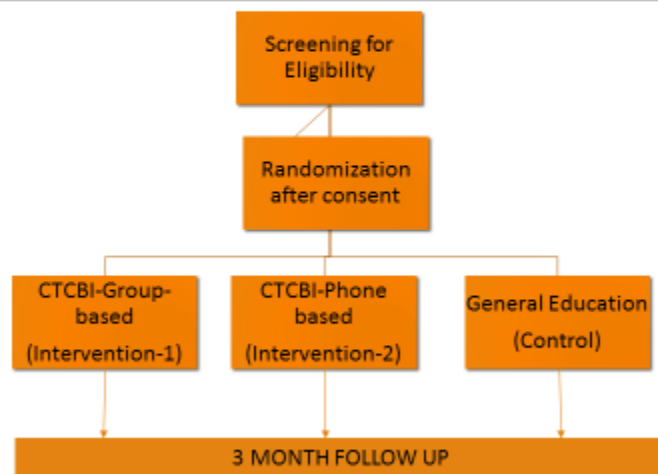




## Study Flow Chart

## Study Flow-Chart

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## Schedule of Procedures for the Duration of the Study

**Table: Schedule of Procedures for the Duration of the Study**

Phase	Training and Finalizing Intervention Procedures	Screening and Enrolment	Baseline		Intervention		Post-intervention	
Months	1-2	3-4	3-4	R A N D O M I Z A T I O N	5-7		8-12	
No. of Patient Visits	0	1	1		2-7 (only group CB-CT)	8	9	Data-Analyses, & Study closeout
Eligibility Screening	-IRB approval, - Training of Staff - Study Advertisement	X						
Informed Consent		X						
HbA1C			X			X	X	
Anthropometrics and Demographics			X			X	X	
Lipid profile			X			X		
Blood pressure			X			X	X	
Questionnaires			X			X	X	
Evaluation					X	X	X	

## A. Background and Rationale

There are significant disparities relating to quality of care and diabetes outcomes among racial and ethnic minorities.<sup>1</sup> African Americans have a higher prevalence of Type-2 Diabetes Mellitus (T2DM) and two to four times the rate of renal disease, blindness, and amputations compared to Whites.<sup>2-3</sup> Inadequate diabetes self-management in this subgroup leads to poor glycemic control, higher complications rates, and more premature deaths. Further, low healthy literacy, limited access, and stress compound this problem, and are barriers to effective diabetes self-care and contribute to these disparities especially among African Americans.<sup>4</sup> Patient's culture, socio-economic status, and psychosocial factors such as coping skills play a big role in diabetes self-care. Diabetes interventions that emphasize collaboration and patient "empowerment" with knowledge, skills and self-efficacy have demonstrated positive effects on glycemic control.<sup>5, 6</sup> The role of Behavioral theory is foundational in understanding behavior change among patients in the self-management of diabetes.<sup>7</sup> Further culturally tailoring increases acceptance and effectiveness of diabetes self-management.<sup>8</sup> Thus T2DM self-management interventions that are grounded in Behavioral theory and are congruent with patient's cultural patterns are likely to be effective, but need to be further tested for improving outcomes in high-risk subgroups such as African Americans.

The aim of our pilot study is to test the feasibility and acceptability of a culturally tailored, cognitive behavioral intervention (CT-CB) program using a group-based vs. a web-based format, and determine if it can improve diabetes self-management among African Americans compared with usual individual based care at the clinic. Our study is translational as it involves the adoption of an established intervention (Cognitive behavior therapy) for improving clinical diabetes outcomes amongst a high-risk population subgroup (African Americans). Besides testing the feasibility and acceptability of the proposed intervention in new formats, the pilot will allow us to identify new clinical questions and would allow us to build a larger scale comparative effectiveness trial.

## B. Experimental Design and Novelty

Primary care physicians manage a majority of patients with type-2 diabetes, but limited time with patients hinders efforts to achieve desired clinical outcomes. Successfully caring for the medical and psychological needs of the patients requires innovative strategies. Effective diabetes self-management that integrates education with behavior strategies such as goal setting has been shown to improve diabetes outcomes and patient satisfaction.<sup>9,10</sup> Cognitive behavioral therapy (CBT) is one such effective strategy that focuses on modifying beliefs, attitudes, and behaviors among patients with chronic conditions including diabetes but has not been specifically tested for African American patients.<sup>11,12</sup> We will evaluate a Culturally-Tailored Cognitive Behavior intervention (CT-CB) for African American patients in a randomized controlled pilot and test the feasibility of this intervention in two formats - a face-to-face coaching in a group format and individual tele-sessions of CBT over the web. Our CT-CB program will have modules on stress management, relaxation exercises, values clarification, problem solving, and decision-making. It will be implemented by our intervention team, led by a health psychologist in partnership with an African American patient panel. Both the group-based and web-based format of the CT-CB intervention can potentially be integrated and scalable in a primary care setting.

Interventions that are informed by theory-driven behavior change models are more successful and lead to lasting changes.<sup>13,14</sup> We seek to test the feasibility, acceptability and likely effectiveness of a culturally tailored, cognitive behavioral intervention (CT-CB) program aimed at improving diabetes control among African American patients. The design of our pilot study will overcome some of the main limitations of prior studies and will include a culturally appropriate and tailored behavioral intervention developed in collaboration with African American patients. First, the curriculum is culturally tailored, using qualitative data from users, to take into account preferences (such as diet, modalities for physical activity and stress reduction) of African Americans in a way that is personalized and respects their cultural preferences. Second, our intervention will be tested in two formats – group-based and web-based sessions. The group-based CT-CB will effectively use the interactions and experiences of the group members as the vehicle of change. The tele-health format (via web) has the benefit of personalization. It also can avoid the hassle for patients (particularly for older patients) to drive to a facility increasing the likelihood of treatment engagement. On the other hand, these participants will not have the benefit of group-interactions. The widespread distribution of mobile webs across socio-economic, racial, gender and age – groups make them a promising platform to provide simple yet effective follow up for diabetes self-management programs. Third, not having an established PCP will not be a barrier for inclusion in the program. Prior interventions have targeted patients who are already well established within the health system with a primary care physician. However, the patients most at risk for poor health outcomes are the ones who rely on urgent care facilities and Minute clinics for routine care. Our program will seek active referral from patients seen in partnering urgent care facilities and Minute clinics with uncontrolled diabetes. Finally, our study will report both secondary outcome measures (HbA1C) and process measures (such as diet and physical activity adherence) in order to fully understand the effectiveness of the program delivery.

## C. Research Strategy

### C.1 Inclusion and Exclusion Criteria

Forty Five African American participants with a diagnosis of diabetes will be recruited for the study.

#### *Inclusion Criteria:*

1. Age: 18 years or older
2. Fluency in English
3. African American
4. HbA1C>8%

#### *Exclusion Criteria*

Patients, who have no web access, using an insulin pump, are pregnant, have active substance abuse including alcohol, have severe hearing, visual impairment or other physical disabilities that would be a barrier for participating in-group or web sessions will be excluded.

### 3.2 Study Recruitment

African American participants with a diagnosis of diabetes will be recruited from primary care clinics at Emory. Potential participants will be identified through community activities, health fairs, and patient referrals. Patients will be contacted via letter or web call from the investigator team with a description of the study. CONSORT guidelines will be followed for the study procedures. Below we describe our recruitment venues:

(1) Chart reviews of Emory Dunwoody patients and onsite clinic recruitment. Referral from physicians.

(2) Patient lists and Referrals from other Primary Care clinics at Emory; Emory Specialty Associates

(3) Community-based recruitment: Community education sessions in local neighborhoods e.g. churches or will be conducted and attendees will be invited to participate in this study. We have ongoing partnership with local groups such as the Healthy Heart Coalition in Atlanta that will help in the publicity of the program.

(4) Physician recruitment: Local physicians (primary care or specialty physicians) will be informed of the study and its criteria and provided information about referral to the study personnel. In addition, flyers for the study will be posted at outpatient areas in the local medical facilities.

(5) Participant recruitment from the community via advertising in local newspapers and radio

(6) Patients who meet the criteria and are already being followed at Emory Clinics will be contacted via phone to gauge their interest in the research program. A team member of the research staff will give a call to those patients only who have initially consented with Emory to be contacted for research studies. A screening consent and standardized phone script will be used for contacting these patients.

### 3.3 Screening Visit and Informed Consent

Potential participants identified by above strategies will be contacted by web or email to provide additional details regarding the study and establish whether basic inclusion criteria are met. At the first screening contact, participants will give verbal informed consent and will be interviewed by a study staff to determine eligibility. If patients are deemed eligible, they will complete written informed consent, study questionnaires, and lab testing at the clinic. A clinic visit will be required pre and post intervention to allow for study measurements

A total of 45 African American participants will be recruited. The recruitment will be done at Emory Dunwoody Primary Care Clinic, which already has a higher proportion of African American population— a subgroup vulnerable to diabetes complications. The participants will undergo baseline survey procedures including demographics, self-administered questionnaires on health behaviors, dietary intake (using a 24-hour recall test), health status and medical history, anthropometrics and blood pressure. Trained study staff will also conduct neuropsychological tests including language and memory tests, attention and executive function tests, clinical diagnosis, activities of daily living (ADL).

#### 4.4 Randomization and Blinding

Upon completion of baseline testing, each participant will be assigned to either the CT-CB intervention (group-based or web-based), or to the individual based usual care group (control condition) using a ratio of 1:1:1 for a **duration of 12 weeks**. Assignments will be based on a computer-generated random number sequence. Patients, clinical, and research staff will not be aware of patient's group assignment until after they have consented to participate and a sealed envelope with the randomization group is opened. Research staff conducting the psychological, physical, outcome assessments, and study analyses will be blinded to participant's group allocation. To minimize bias, participants in the intervention group will be asked to refrain from disclosing their group assignment to study staff who collect data and questionnaires. Due to the overt nature of the CT-CB approach, the investigators and participants in the intervention group will not be blinded. (Figure)

#### 4.5 Study Arms

**Group-based Culturally Tailored Cognitive Behavioral intervention (CT-CB):** The goal of our CT-CB intervention is to improve adherence to dietary habits, physical activity, and self-management activities (such as glucose self-monitoring, feet check at night), by using exercise and food planning education as well as cognitive behavioral interventions with the ultimate goal of an improvement in HbA1C. The group-based CT-CB intervention will include six 1-hour group sessions held biweekly for twelve weeks. Each sixty-minute session will consist of 15 minutes of diabetes education regarding exercise and food planning and approximately 45 minutes of CT-CB presentations/engagement activities. A physician and a Behavioral Interventionist will collaboratively facilitate the group sessions. Participants will be encouraged to bring along their family members or friends for support. The Behavioral psychologist will be responsible for the integrity of the intervention. (Table)

**Web-based Culturally Tailored Cognitive Behavioral Intervention (CT-CB):** Participants in the web-based CT-CB will be asked to reserve a 1 hour period for a web call from the Behavioral Interventionist team. Text reminders will be sent to the participants prior the sessions. During this period, approximately 15 minutes will be reserved for diabetes exercise and food planning education and approximately 45 minutes of CT-CB engagement activities. This intervention will use an established protocol incorporating the same elements of cognitive behavior change as in the group-based CT-CB, but without the opportunity for group-interaction. The frequency of the web-based CT-CB will be similar to the group-based CT-CB, i.e. 6 sessions that occurs every two weeks for three months.

**Usual Care group:** Usual care group participants will continue to receive care and follow up from their primary care providers as per the American Diabetes Association guidelines with log books, education regarding self-management strategies and appropriate referrals as needed. The inclusion of the general education control group (usual care) along with the group-based CT-CB and web-based CT-CB will allow for a more realistic examination of recruitment, randomization, and implementation of procedures.

**Post-intervention follow up and Focus Group:** Both the group –based and the web-based CBT intervention group will be followed for an additional three months to study for possible diminution of treatment effects over time. At the end of the study, a focus group of intervention participants will be used to explore the experiences, attitudes and further needs of participants.

### 3.6 Primary and Secondary Outcomes

Chart review and questionnaires will be used to ascertain patient demographic data. The primary outcome of our pilot is feasibility and acceptability. **Aim-1: Feasibility is operationalized as patients enrolled as per target with a loss to follow up of no more than 20%. Acceptability will be operationalized as session attendance and will be considered adequate if at least 70% of the sessions are attended. In addition, we will collect qualitative data using patient surveys to learn about patient acceptability of the intervention and their likelihood of continuing to use these techniques in future.** Secondary outcomes that are of high interest include a change in glycated hemoglobin (HbA1C) at baseline vs. 3 months; the Patient Health Questionnaire (PHQ-9) to assess depressive symptoms<sup>15</sup>; Diabetes Distress Scale<sup>16</sup>, anxiety (Brief Symptom Inventory)<sup>17</sup>, self-efficacy<sup>18</sup>, quality of life (SF-12)<sup>19</sup>, Diabetes Health Belief Scale<sup>20</sup>. Process measures such as Patient Activation Measure (PAM-13)<sup>21</sup>, medication adherence questionnaire<sup>22</sup>, session-participation, glucose self-monitoring, diet and physical activity will also be measured at each visit. Other clinical measures related to diabetes such as blood pressure, body mass index, lipid levels would be measured pre and post intervention. Adverse events such as episodes of hypoglycemia, diabetes –related hospitalizations, and ER or urgent care visits will be ascertained during the study visits. Emory’s Institutional Review Board will evaluate the study’s protection of human subjects plan and a Data and Safety Monitoring Board (DSMB) will review study procedures and any adverse events. Trained study staff will do all the laboratory measurements and the intervention sessions.

### 3.7 Data Analytic Procedures

**Sample Size** – Our pilot sample size (of 45 participants) is based on the pragmatics of recruitment, budgetary constraints, and the necessities for examining feasibility. Therefore, in the absence of any inferential statistical test and hypothesis testing we do not present any power analyses. We however outline below the framework for analyzing the statistical approach needed for the study for efficacy of the intervention to be tested in future.

**Statistical Analysis- Aim-1: Feasibility and acceptability will be calculated as outlined in the section on “Primary and Secondary Outcomes”. To further assess acceptability we will conduct qualitative interviews with participants at the end of intervention (3 months) and post-intervention follow up at 12 weeks. An interview topic guide will be developed (overall experience, preferences and narrower probes regarding both positive and negative aspects) and participant semi-structured interviews will be recorded and transcribed verbatim.**

**Aim-2a:** Analyses of intervention effects will be conducted on an intent-to-treat basis and all p-values will be two-tailed. Descriptive statistics such as mean and standard deviations will be used to describe the distribution of quantitative variables. Linear mixed effects models will be used to examine the effects of CT-CB treatment and the interaction of treatment and significant demographic covariates selected using stepwise selection procedure with 0.05 as cut off for entering the model. The linear mixed-effects models accounts for the correlations among repeated measurements within the same subject. The study analysis will compare the mean twelve week HbA1C of the CT-CB interventions (group and web-based) vs. the control group.

**Aim-2b:** As an exploratory exercise, we will also stratify the results as 1) mild uncontrolled diabetes (HbA1C<9%) and severe uncontrolled diabetes (HbA1C >9%) and 2) < 65 years (younger) vs. > 65 years (older) and men vs women. Other secondary analyses will test the null hypothesis of no difference between the intervention and control group with other clinical outcomes (such as anxiety, blood pressure). P-value from between group comparisons will be



Bonferroni adjusted within outcome model since three pairwise group comparisons will be performed. Adverse events (such as hypoglycemia, ER visits) will be reported as a percentage of patients affected in each group. The trial will be registered at ClinicalTrials.gov and will follow usual protocol of randomized control trial per CONSORT guidelines. SAS software will be used for all data analyses.

### 3.8 Data collection and Quality Assurance

Data collected during interviews and exams will be documented on trial-specific data forms. Biomedical information will be saved in digital formats on a HIPAA-compliant server.

## Data Management

Once a subject is enrolled into the study, he/she will be assigned a unique identifier number and be referred to by initials and the study number only. Only research team members will have access to the files. Data will be entered on a web-based secure trial data system (which is HIPAA compliant); the trial database will include for all variables an electronic data audit of data edits (who, when, and why). A data query report (including missing, out of range, and logic checks) will be generated by the trial statistician. The investigators will keep subjects' medical records private as far as the law allows. The IRB and officials of the sponsor/funding agency will have access to these records as needed within legal guidelines. If study results are published in journals or presented at meetings, we will not use the subjects' names.

## Quality Assurance

The PI and co-investigators will train research personnel. The process of training on data forms completion, neuropsychological assessment and subject evaluation will be documented in a training log for each study personnel.

To assess protocol compliance and quality of data collected, the PI along with another investigator will randomly and on intervals review data obtained. In addition, assessment of personnel competencies in obtaining data will be performed.

## Protocol Deviations

Every attempt will be exercised to maintain compliance with the approved study protocol. In the event when a deviation is noted, the Emory IRB will be notified as required by IRB Policies & Procedures only if the deviation affects the rights or welfare of subjects, the safety of subjects, the willingness of subjects to continue with study participation, or the integrity of the research data. The PI or designated personnel will conduct an investigation about the setting, reasons, and potential remedies that need to be instituted to rectify the deviation and prevent future similar instances. This protocol, the informed consent document, and any subsequent modifications will be submitted and reviewed by the Emory IRB.

## Consenting Procedure

A signed consent form will be obtained from each participant. A single informed consent form will describe both the screening and study procedures. The consent form will describe the purpose of the study, the procedures to be followed, and the risks and benefits of participation. A copy will be given to each participant and this fact will be documented in the participant's



study record.

### **Data and Safety Monitoring Plan**

The PI will be responsible for monitoring the data and safety of the patients. All Investigators and study staff will be CITI- certified before the start of the study. Data and feedback from the participants will be reviewed on a bimonthly basis. Adverse events will be reported to the Institutional Review Board. Any unforeseen adverse reactions that develop among patients will be discussed with the Data and Safety Monitoring Board (DSMB). The DSMB will meet on a quarterly basis to review safety data and will be composed of a minimum of three individuals with expertise in clinical trials. These will include a statistician, a geriatrician, and a representative(s) from the Institutional Review Board. This board will be responsible for monitoring adverse events and will reported them to the Institutional Review Board (IRB)

## **3.9 Participant Safety**

### **Participant Confidentiality**

Only the investigators will have access to information about a particular subject. The subject's primary care physician will only be notified if the subject agrees. To maintain confidentiality, subject data will be referenced by number and stored in locked computer files and cabinets. Identifying information about a subject will not be used during the discussion, presentation, or publication of any research data. Only research team members will have access to the files. Data recorded and stored on the computer will be backed up to a disc and stored with the paper files. Participants will not be given any results of the research procedures unless there is a medical necessity. This will be clearly stated in the informed consent process.

### **Potential Benefits and Importance of Knowledge to be Gained**

The risks to the participants are minimal, relative to the importance of the knowledge to be gained. This pilot will improve our knowledge about behavioral interventions for high-risk patients with diabetes. Understanding the mechanisms and format for the delivery of such behavioral interventions (group-based vs. web-based) has the potential to improve clinical outcome and impact diabetes care disparities.

### **Potential Risks**

The potential risks of this study are minimal and related to the following study procedures: blood draw. An experienced phlebotomist at Emory Dunwoody Clinic using sterile technique will perform blood draws. The risks of blood draw are minimal and include infection, bleeding, anemia, and damage to the vein. Only a small amount of blood is required for assessment of HbA1C and Lipid profile (<2 cc). The participant's physician will be informed of any results that are relevant to patient care.

### **Withdrawal of Participants**

Participation is voluntary. Participants can withdraw from the study or refuse any of its parts if they so choose to at any time without any consequence.

### **Inclusion of women, children and minorities**

We anticipate that ~50% of the study subjects will be female. Absence of pregnancy will be demonstrated by blood or urine testing prior to randomization (in female subjects of child bearing potential only). The intervention is focused on African American participants only as such Hispanics and other ethnic minorities will not be included. No patients under the age of 18 will be recruited in this study.

### **Participant Compensation**

Subjects will be compensated with gift cards for their effort and time. Participants will be given \$25 for each study visit – first, 3month, and 6 month. Pedometers used during the study intervention will be given away free at the end of the study. The CBT intervention will be provided free of cost to the participants.

### **Study Discontinuation**

The study may be discontinued at any time by the investigators, the Emory IRB, the OHRP or other government agencies as part of their duties to ensure that research participants are protected.

### **Publication of Research Findings**

Publication of the results of this trial will be governed by the policies and procedures of Emory and the funding agency. Participants can receive a copy of the study results if they are interested.

### **Drugs or Devices**

Our study does not involve any investigational drugs or devices that will be used for the participants.

## **3.10 Study Administration and Funding Source**

**Study Time Frame:** Research will begin upon IRB approval (anticipated in January 2018) and will end in July 2019

**Funding Source:** P30 GCDTR (Georgia Center for Diabetes Translation Research)

**Study Key Personnel:** Listed on Page-2 Study Roster. Behavioral interventionist is yet to be hired.

**Study Site:** The site for this demonstration project will be the Emory Family Medicine Clinic at Dunwoody (4500 North Shallowford Road, Atlanta). Providers at this facility (#36) have been serving the community residing in the northern region of Atlanta since 2004. Approximately 11,000 individual patients receive care at the clinic each year with 24,000 encounters. The clinic has a large private didactics room that will be ideal for the patient group sessions. The facility is a National Center for Quality Assurance accredited, Level 3 (highest) Patient-Centered Medical Home (PCMH) that aims to enhance the delivery of comprehensive primary care to children, adolescents, and adults. 60% of the patients are African Americans. The study site also has a behavioral psychologist who will be part of the study. The clinic has been a site of several prior pilot studies, and partners for recruiting patients for studies at Emory Healthcare and the American Academy of Family Physicians DARTNet (Distributed Ambulatory Research in Network).

## D. Study Impact and Future Directions

Culturally tailored, cognitive-behavior therapy can improve psychological health and instill better coping strategies for vulnerable population groups. CBT-based approaches may be beneficial in diabetes care and could be potentially incorporated into diabetes care management teams. Our pilot study would demonstrate if a socio-culturally adapted behavioral intervention for African American patients will be feasible in primary care setting and has the potential to improve outcomes and reduce disparities in diabetes care. Behavioral interventions that are culturally tailored and drawing on the theoretical principles of cognitive behavior therapy could aid the successful translation of such interventions for use in routine clinical practice. This approach is also in line with current efforts to make the delivery of health care more patient-centered.

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## Appendix A

# Is your diabetes out of control?



We are looking for

- African American men or women
- with uncontrolled diabetes
- No major physical disability

Participants will be offered a free six month lifestyle program that can likely help with diabetes self-management. Compensation for time and travel will be provided to all participants. Enrollment is limited to 45 participants.

For more information, **please contact at XYZ at web no. ....**

